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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,961

07/11/2005

Charles C. Hart

2877-USP-PCT-US

8849

21378

7590

08/06/2007

APPLIED MEDICAL RESOURCES CORPORATION

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

08/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,961

Applicant(s)

HART ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 16-30, 33 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 16-30, 33 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 25 May 2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 11, 14, 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kees (US Patent 3,827,438) and Davis, et al. (US Patent 6,527,786).

Claims 1: Kees' 438 teaches a one-piece clip having a first jaw (18) having a distal end (left of number 18 in Figure 1) and a proximal end (near element 10 in Figure 1), a second jaw (19) having a distal end (left of number 19 in Figure 1) and a proximal end (near element 10 in Figure 1) and opposed to first jaw (18), a first arm (13) attached to the proximal end of the first jaw (18) to pressably close or open the first jaw, a second

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arm (14) attached the proximal end of the second jaw (19), wherein the clip is constructed from a single wire (column 1, line 10-13). Kees'438 does not teach the use a coating on the jaws, and the use of another coating on the remainder of the clip.

Davis'786 teaches a ligating clip that can have either serrated jaws or a sticky coating in order to improve the clip's traction (column 5, lines 63-68). Soft elastomers are well known in the art to be a sticky coating (column 8, lines 25-27). Davis'786 further teaches that the clip can be made out of metal, like stainless steel or titanium. It is well known in the art that these materials comprise a thin layer of oxide coating that makes them less prone to corrosion. It would have been obvious to one skilled in the art at the time the invention was made to modify the clip taught by Kees'438 with a sticky coating as taught by Davis'786 in order to increase the traction of the clip and make it less traumatic and to modify the clip taught by Kees'438 with an oxide coating over the rest of the clip in order to aid in preventing corrosion of the clip.

Claim 2: Kees'438 teaches that the arms are resiliently pressed against each other in the closed position (see Figure 1).

Claim 3: Kees'438 teaches a tensioning device (12) connected to the first jaw (18) and the second jaw (19) to bias the jaws into the closed position (see Figure 1 and column 2, lines 12-15).

Claim 4: Kees'438 teaches that the tensioning device is a coil (12) having at least 1 turn (see Figure 2).

Claim 5: The device taught by Kees'438 is capable of having the tension, strength, and holding characteristics of the tensioning device varied based on the

number of turns in the central coil and the hardness/temper of the wire because it is of the same design, and made with metal which can have the material properties/characteristics modified in similar ways (such as tempering, type of metal used, etc.).

Claim 6: Kees'438 teaches that the wire has a cross-section having a geometric shape.

Claim 7: Kees'438 teaches that the wire is folded in one plane (see Figure 1 and 2).

Claim 8: The device taught by Kees'438 is capable of being curved, bent, or shaped to provide access to a specific area of a procedure because it is made of a similar material (metal, which is malleable) and its intended use is for the same type of procedure (aneurysm clip).

Claim 11: Kees'438 teaches that the clip has an atraumatic distal end (tip left of numbers of 18 and 19 in Figure 1).

Claim 14: Kees'438 in view of Davis'786 discloses the invention substantially as claimed. However, Kees'438 does not teach a sticky coating made of an elastomer. Davis'786 teaches that the sticky coating can be made of soft elastomers such as silicone rubber (column 8, lines 25-27). It would have been obvious to one skilled in the art at the time the invention was made to improve traction on the jaws of a clip by coating the jaws because it increases the gripping ability of the clip because it is soft and sticky.

Claim 18: Kees'438 teaches that the clip is used as an aneurysm clamp (column 1, lines 3-4).

Claim 19: The clip taught by Kees'438 is inherently disposable.

Claim 20: the clip taught by Kees'438 is inherently reusable.

Claim 21: The device taught by Kees'438 is capable of being formed from stamping because it is made from a flat ribbon of metal (column 1, lines 10-12).

Claim 22: the device taught by Kees'438 is formed from a pre-formed ribbon of metal (column 1, lines 10-12).

Claim 23: The device taught by Kees'438 is capable of being formed from a die-cut perform because it is made of a flat ribbon of metal that is capable of being die-cut.

Claim 24: The device taught by Kees'438 is capable of being photo-chemically cut, etched pre-form, or sheet of preformed ribbon because it is made from a the same material (flat ribbon of metal).

Claim 25: The device taught by Kees'438 is capable of being formed from a plurality of pre-formed generated from a plurality of pre-forms generated on a single sheet because it is made from the same material (flat ribbon of metal).

Claims 26, 28, 29, 30, 33, 35, 36, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt, et al. (US Patent 5,758,420) in view of Davis'786.

Claim 26: Schmidt'420 teaches a method for manufacturing an aneurysm clip that includes winding a single wire (12) around a mandrel in order to form a central coil (22), a first extension (26), and a second extension (34) (column 9, lines 55-67). Next,

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the first extension (26) is bent back on itself to form a first jaw (32) then bending the second extension back on itself to form a second jaw (40). Then, returning the first bent extension (32) and the second bent extension (40) back to the central coil (22) so that the first and second extensions extend rearward in a direction opposite of the first and second jaws to form a first handle portion (26) and a second handle portion (34).

Schmidt'420 does not teach the use of a first coating on the jaws and a second coating on the rest of the clip.

Davis'786 teaches a ligating clip that can have either serrated jaws or a sticky coating in order to improve the clip's traction (column 5, lines 63-68). Soft elastomers are well known in the art to be a sticky coating (column 8, lines 25-27). Davis'786 further teaches that the clip can be made out of metal, like stainless steel or titanium. It is well known in the art that these materials comprise a thin layer of oxide coating that makes them less prone to corrosion. It would have been obvious to one skilled in the art at the time the invention was made to modify the clip taught by Schmidt'420 with a sticky coating as taught by Davis'786 in order to increase the traction of the clip and make it less traumatic and to modify the clip taught by Schmidt'420 with an oxide coating over the rest of the clip in order to aid in preventing corrosion of the clip.

Claim 28: Schmidt'420 teaches that the first (32) and second (40) bent extensions include an atraumatic distal end (column 1, lines 65-67).

Claim 29: Schmit'420 teaches that the first and second bent extensions (32, 40) are formed to rest upon the coil (see Figure 10).

Claim 30: The method taught by Schmidt'420 inherently allows for configuring the clip for specific areas of a procedure (column 12, lines 5-11).

Claim 33: Schmidt'420 in view of Davis'786 discloses the invention substantially as claimed. However, Schmidt'420 does not teach a sticky coating made of an elastomer. Davis'786 teaches that the sticky coating can be made of soft elastomers such as silicone rubber (column 8, lines 25-27). It would have been obvious to one skilled in the art at the time the invention was made to improve traction on the jaws of a clip by coating the jaws because it increases the gripping ability of the clip because it is soft and sticky.

Claims 35 and 36: If a polymer coating, as taught by Davis'786 is placed over the jaws, it is removable, and therefore must be reusable and disposable. It would have been obvious to one skilled in the art at the time of the invention to modify the jaws taught by Schmidt'420 with a removable coating as taught by Davis'786 to place a reusable coating over the jaws in order to improve the traction grip because removable coatings can be replaced.

Claim 39: Schmidt'420 teaches that his steps may be modified in order to facilitate precision manufacturing (column 3, lines 28-29).

Claim 40: Schmidt'420 teaches his manufacturing processes uses a cylindrical rod (column 3, lines 11-13).

Claims 1, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vien (FR 1.029.119) and Davis'786.

Claim 1: Vien'119 discloses a clip made of a single wire comprises a first jaw (2), a second jaw (second element 2), a first arm (3), and a second arm (second element 3), wherein the clip is constructed from a single wire (Figure 1). Vien'119 does not teach the use a coating on the jaws, and the use of another coating on the remainder of the clip.

Davis'786 teaches a ligating clip that can have either serrated jaws or a sticky coating in order to improve the clip's traction (column 5, lines 63-68). Soft elastomers are well known in the art to be a sticky coating (column 8, lines 25-27). Davis'786 further teaches that the clip can be made out of metal, like stainless steel or titanium. It is well known in the art that these materials comprise a thin layer of oxide coating that makes them less prone to corrosion. It would have been obvious to one skilled in the art at the time the invention was made to modify the clip taught by Kees'438 with a sticky coating as taught by Davis'786 in order to increase the traction of the clip and make it less traumatic and to modify the clip taught by Kees'438 with an oxide coating over the rest of the clip in order to aid in preventing corrosion of the clip.

Claim 9: Vien'119 teaches that the first arm and second arm (3) have a ring shaped proximal tip to enhance grip (see Figure 1).

Claim 10: The ring shaped proximal tip taught by Vien'119 is capable of being attached to a tether or suture to allow for easy tracking of the tip.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kees'438 and Davis'786, as applied to Claim 1, in further view of Schmidt'420.

Kees'438 and Davis'786 teach the limitations of Claim 16, except for the use of a tool to reshape the jaws of the clip.

Schmidt'420 discloses the use of a mandrel to shape the clip (column 9, lines 55-67). It would have been obvious to one skilled in the art at the time the invention was made to use a mandrel, as taught by Schmidt'420, on the device taught by Kees'438 and Davis'786 to customize the shape of the clip in order to use it in various applications.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kees'438 and Davis'786, as applied to Claim 3, in further view of Yoon (US Patent 5,217,473).

Schmidt'420 and Davis'786 teach the limitations of Claim 3, except for the use of a traction rod to deploy the clip.

Yoon'473 teaches the use of a rod (14) that can be used to place the tensioning device (12) of the clip (10) at the desired location during the procedure in order to place in the clip in places in accessible to the hands. It would have been obvious to one skilled in the art at the time the invention was made to use a rod a rod as taught by Yoon'473, on the device taught by Kees'438 and Davis'786 in order to aid in deployment of the clip in hard to reach locations in the body.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt'420 and Davis'786, as applied to Claim 26, in further view of Vien'119.

Schmidt'420 and Davis'786 teach the limitations of Claim 27 except for bending the first and second proximal portions to enhance grip.

Vien'119 teaches that the first and second handle portions are bent back to form a grip, in order to provide a larger surface for the user to grip as shown in Figure 1. It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Kees'438 and Davis'786 by bending back the first and second handle portions as taught by Vien'119 in order to create a larger gripping area.

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt'420 and Davis'786, as applied to Claim 26, in further view of Vien'119.

Schmidt'420 and Davis'786 teach the limitations of Claim 37 except for the use of a ring-shaped proximal tip. Regarding Claim 37, Vien'119 discloses that the first arm and second arm (3) have a ring shaped proximal tip to enhance grip (see Figure 1). Regarding Claim 38, the ring shaped proximal tip taught by Vien'119 is capable of being attached to a tether or suture to allow for easy tracking of the tip. It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Schmidt'420 and Davis'786 with the ring shaped tip taught by Vien'119 because it helps track and enhance the grip of the device.

Response to Arguments

Applicant's arguments filed 25 May 2007 have been fully considered but they are not persuasive.

Applicant argues that the coating on the jaws must provide improved traction and increased padding. Applicant argues that a sticky coating does not provide increased

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padding. This is not persuasive because a sticky coating, such as silicone rubber (column 8, lines 25-27) is inherently atraumatic because of its elastomeric qualities. Further, a sticky coating provides an extra layer of a softer material because, in order to be sticky, the surface must be able to change shape in order to increase the surface area that is contacting the item being grasped.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-


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6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alt. Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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